Technical specification

Ventilation mode

IPPV, V-A/C , P-A/C , P-SIMV ,V-SIMV , PCV , PSV , SPONT/CPAP ,

PRVC(optional) ,APRV(optional) ,Duol evel(optional) ,SIGH, MANU

Ventilator parameter

Tidal volume (Vt)	0, 20 ~ 2000 ml
Frequency (Freq)	1 min~ 100min
Oxygen concentrat1on	21 % ~ 100%
I:E	4: 1 ~ 1: 8
PEEP	0 cm比0 ~ 40 cmH20
Pressure limit	20 cm 比 0 ~ 100 cmH20

Pressure triggering sensitivity (Ptr)	-20 cm比O~ O cm比0 (Based on PEEP)
Flow triggering sensitivity (Fir)	0.5 cm比0 ~ 30 cmH心
SIGH	O(off) 1/100 ~ 5/100
Apnea ventilation	OFF, 5 s ~ 60 s

Monitoring parameter

Frequency (Freq)	0/min ~ 1OO/m1n
Tidal volume (Vt)	0 ml~ 2500 ml
MV	0 L/min ~ 99L/m1n
Airway pressure	O cm 比 O ~ 100 cmH 心
Dynamic lung compliance monitoring	1 mL/cmH,O ~ 1000 mL/cmH 心
Oxygen concentrat1on	15 % ~ 100 %

Packing size

Main engine: L 560 * W 560 * H 605 mm

G.W.: 35 KG, N.W.: 17 KG

Air compressor: L 683* W 687 * H 1140 mm

G.W.: 100 KG, N.W. : 65 KG

Alarm and protection

The AC power failure alarm	Power failure or no connection
Internal backup battery low voltage alarm	11.3 ± 0.3 V
No tidal volume	No tidal volume within 6 s
High minute volume alarm	5 L/min ~ 99 L/m1n
Low minute volume alarm	1 L/min ~ 30 L/min
High airvvay pressure alarm	20 cm比O ~ 100 cmH心
Low airvvay pressure alarm	O cm 比 0 ~ 20 cmH 心
High oxygen concentration alarm	19 % ~ 100 %
Low oxygen concentration alarm	18 % ~ 99 %
Continuous pressure alarm	(PEEP+ 1.5 cmH心) over 16s
Suffocation warning	5 ~ 60 s
Fan error	Show on screen
Oxygen deficit	Show on screen
The maximum limited pressure	< 12.5 kPa

Working condition

Gas source	O_2 Air
Pressure	280 kPa - 600 kPa
Voltage	220 V ± 22 V
Power frequency	50 Hz ± 1 Hz
Input power	900 VA(With air compressor)
	250 VA(Without air compressor)

Oscillogram

P-T(Pressure-Time)

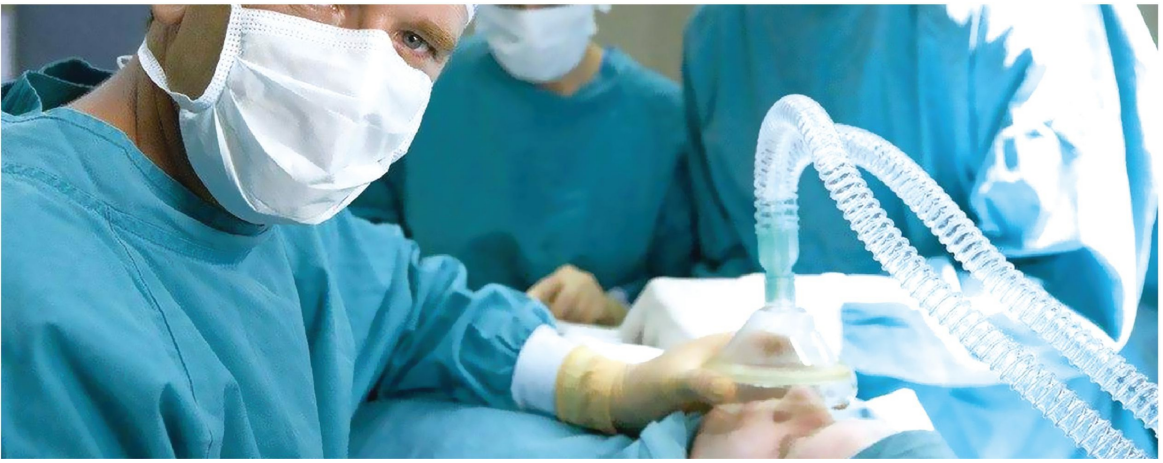
F-T(Flow-Time)

P-V Loop(Pressure-Volume Loop)

Cherish your life, Cherish your health!

S1100 ICU Ventilator

Friendly Powerful Reliable



S1100 ICU Ventilator

Application

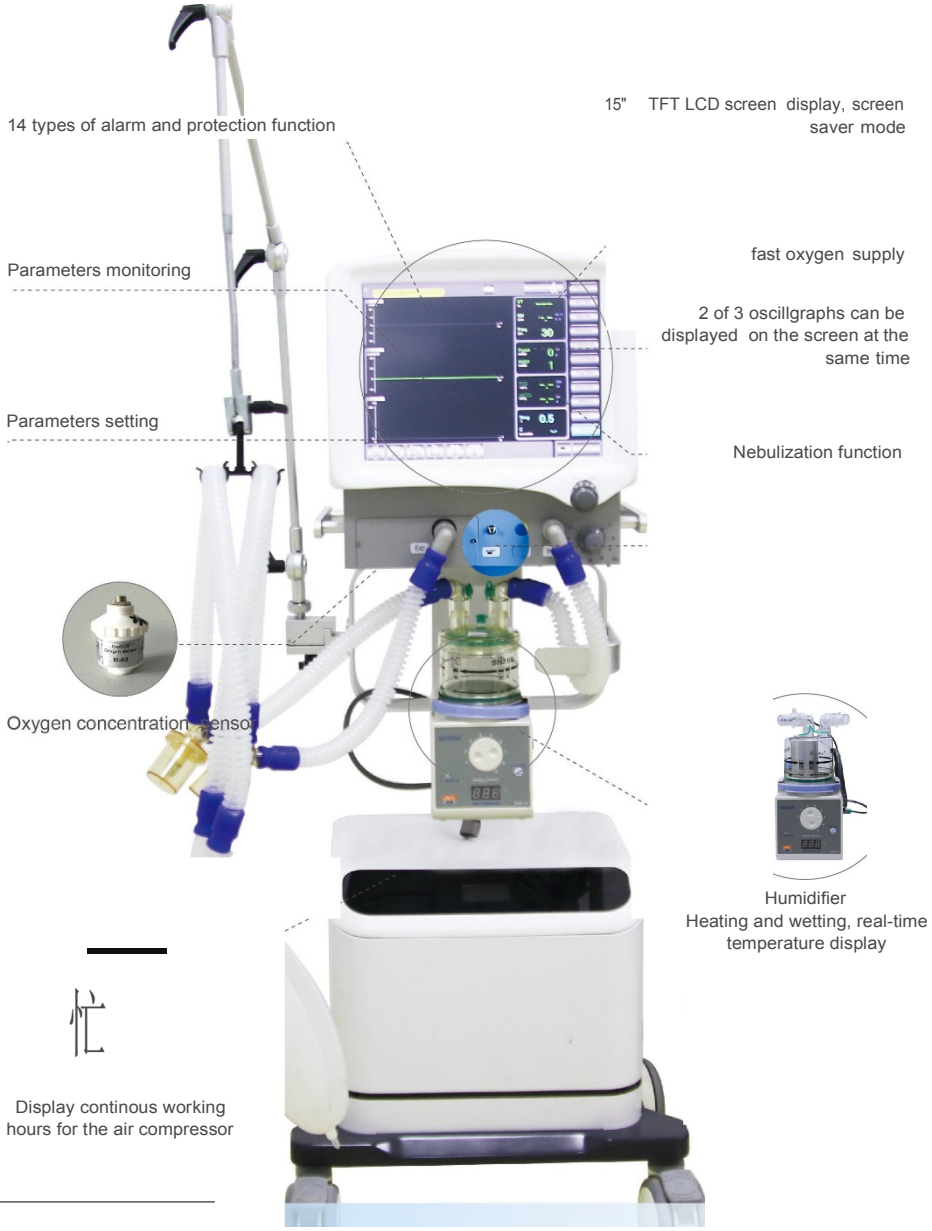
The ventilator makes a good performance in operation room,ICU department and emergency treatment.It used to assist or replace the spontaneous breathing for adult pediatric and neonatal more than 2kg. 25 years experience in Market-oriented ventilator make us professional and reliable, satisfying all your needs in ventilation Due to the flexible configuration, good quality and competitive price, S1100 has soon become the superstar of market

Feature

- 15" TFT screen displays the ventilation parameters, alarm information, and oscillograms, make every operation more easily
- Multiple ventilation mode can meet different clinical requirements.(IPPV A/C PCV SIMV PSV SPONT/CPAP SIGH MANUAL
- 3 oscillograms for your choice, 2 of them can be displayed on the screen at the same time
- Humidifier can heat and wet breathing gas, makes it comfortable for patient to breathe
- Rapid oxygen supply,automatically offer high flow rate oxygen within two minutes
- High temperature resistance breathing circuit is reusable and anti-pollution

Safety

- 14 types of sound and visual alarm information, easier for users to do some error checking and troubleshooting
- Built-in oxygen concentration sensor, ensure stable precision of oxygen concentration
- Easy to move with four casters, easy to stop with two brakes
- Separate design of electronic circuit and gas flow rate keep safe running of ventilator
- Compact long life internal battery can provide emergency power,avoid risk of patient
- Self-check before operation,eliminate system mistake



Friendly Powerful Reliable

Packing list

Name： Ventilator **Type：** S1100

NO.	Name	Specification	Quantity	Unit	Remark	
1.	Main body	2.782.075A	1	PC.	Packing box 1	
2.	Power cord	1.2M	1	PC.		
3.	Air compressor	2.782.134A	1	PC.		Packing box 2
4.	High pressure hose for air compressor	4.472.023	1	PC.		
5.	High pressure O_2 hose	4.472.001	1	PC.		
6.	CO_2 sensor	KM7012	1	PC.		
7.	Power cord	4M	1	PC.		
8.	Fuse	T2A	4	PCS.		
9.	Fuse	T4A	2	PCS.		
10.	Fuse	T10A	2	PCS.		
11.	Fuse	T6.3A	2	PCS.		
12.	Screw	M5X16	6	PCS.		
13.	Serrated saddle	Φ5	6	PCS.		
14.	Hanger		1	PC.		
15.	Humidifier (adult)	SH330	1	PC.		
16.	Breathing tube (C-Ⅰ-1)	(Φ22-Φ22)×800mm	2	PCS.		
17.	Breathing tube(C-Ⅰ-1)	(Φ22-Φ22)×400mm	3	PCS.		
18.	Breathing tube(C-Ⅰ-2)	(Φ22-Φ22)×400mm	3	PCS.		
19.	Breathing tube(C-Ⅰ-2)	(Φ22-Φ15)×800mm	2	PCS.		
20.	Water trap	Adult	2	PCS.		
21.	Y connector	Adult	1	PC.		
22.	Y connector	Child	1	PC.		
23.	L connector		2	PCS.		
24.	Test lung	1L	1	PC.		
25.	Operation manual		1	PC.		
26.	Certificate of Quality		1	PC.		
27.	Packing list		1	PC.		

Main technical specification of S1100

Power supply

- Voltage 100-240 V ~
- Frequency 50 H_Z/60 H_Z
- Input power 80 VA
- Internal power DC12V 4Ah
- Fuse
  - ——Main power T2AH 250V
  - ——Internal power T4AH 250V

Ventilation mode

- ——IPPV
- ——A/C
- ——V-SIMV
- ——P-SIMV
- ——PSV
- ——PCV
- ——SPONT/CPAP
- ——PRVC
- ——APRV
- ——DuoLevel
- ——SIGH
- ——MANUAL

Ventilation parameter adjustment

- Frequency
  - ——Adjusting range 1 /min ~ 100 /min
    (Under SIMV: 1 /min ~ 40 /min
    All mode except SIMV: VT_H 4 /min ~ 40 /min
    VT_L 20/min ~ 100 /min)
  - ——Allowable error ±1 /min or ± (10% setting value), whichever is the greater
- Inhalation time (I:E) (Tinsp)
  - ——Adjusting range 0s ~ 12s(except SIMV mode, I:E 4:1 ~ 1:8)
  - ——Allowable error ± 15 %
- Tidal volume (V_T)
  - ——Adjusting range 0 mL ~ 1500 mL
    And:
    VT_H 250 mL ~ 1500 mL
    VT_L 0. 20 mL ~ 300 mL

——Allowable error ± (10 mL + 10% setting value)

- Minute ventilation（MV）
  ——Max MV
  VT_H ⩾ 18 L/min
  VT_L ⩾ 10 L/min
- PEEP
  ——Adjusting range 0 cmH_2O ~ 20 cmH_2O
  ——Allowable error ± (2 cmH_2O + 5% setting value)
- CPAP
  ——Adjusting range 0 cmH_2O ~ 20 cmH_2O
  ——Allowable error ± (2 cmH_2O + 5% setting value)
- Continuous flow
  ——Adjusting range VT_H 7 L/min ~ 60 L/min
  VT_L 2 L/min ~ 30 L/min
  ——Allowable error ⩾ 3L/min, ±15%
  ⩽ 3L/min, ±0.5 L/min
- Inspiratory trigger
  Pressure trigger（PTr）
  ——Adjusting range −20 cmH_2O ~ 0 cmH_2O（Under PEEP）
  ——Allowable error ±（1 cmH_2O + 10 % setting value）
  Flow trigger
  ——Adjusting range 0.5L/min ~ 30 L/min
  ——Allowable error ⩾ 3L/min, ±15%
  ⩽ 3L/min, ±0.5 L/min
- Pressure control（Pc）
  ——Adjusting range 5 cmH_2O ~ 60 cmH_2O
  ——Allowable error ± (2 cmH_2O + 5% setting value)
- Pressure support（Ps）
  ——Adjusting range 0 cmH_2O ~ 60 cmH_2O
  ——Allowable error ± (2 cmH_2O + 5% setting value)
- O_2 concentration
  ——Adjusting range 21 % ~ 100 %
  ——Allowable error ± 3 % (v/v) or ± 10 % setting value, whichever is the greater
  ——Response time of the VENTILATOR from a volume fraction of 21 % to 90 %
  Vt 500 mL 2s
  Vt 150 mL 2.5 s
  Vt 30 mL 3s
- Holding time（Inhalation platform）（TIP）
  ——Adjusting range 0 ~ 6s(0% ~ 50% inhalation time)

ftJlawable error ±0.1s or ±(10% sett叩 value), whichever is thegreater

- Apnea心 ntilatioo
  -Adjustingrange OFF. 5s - 60s
- Maximal InspiratoryFlow Rate

  MaximalInspiratoryFlow Rate: > 60 Umin
- Max setworking pressure
  （pressure lim ra叨e） 20cmHP - 100cmH,O
- Max pressure < 125cmH,O
- Output MV u心er manualventilation > 2SL加 in
- Nebulizergas maximumoutput pressure<0.2 MPa
  maximumoutput flow> 8 Umin

explanation:

1） set p咚 sure limitvalue to prod心 e maximum 欢 rking pressure(the upper limttd high airway pressure alann)

2）do not use心尹 tivepressure at exhalation

3） maxim叩 Hmit pressure is pressured 归 safetyvalve.

Ventilation parameter Monitoring range

- The folow 巾 g are mon ori闻 parameters under t恼 environment of body temperature and pressu心 saturated
- Fig display:

Parameter	氏, nge	Resolving power	压 uracy
F 函 uency(Freq)	0/mln - 100/min	1/min	± 1/min or ± (10% actual r 函 ing), whi 叩 ver ls t 恼 greater
Tidalvolume(VT)	0 mL- 2000mL	10ml	> SOmL , ±（4.0 mL+1 5% ac t妇 l r邮d 叩 ）
M(iMnutV)e ventilation	OUmln-99Umin	0.1 Umin	（ 50 ml , 必 mL >3Umln. ±（15% actual 『四 叩 ）
(Ppeakl	OcmH,O -100cmH,O	1cmH,O	(3Umin, 心 SUmln ±（2%full sca贮
Oconoentration	15% - 100%	0.1 %	4% actual 泥式i叨） ±[2 . 5 % (v/v) + 2.5 %(00心 entrationlevel)]
Compliance	1～1OOOmUcmH,O	1mL/cmH心	

- Waveform display:
  ——Time- airway pressure（under all modes）
  ——Time—flow（under all modes）
  ——pressure volume loop（all modes）

Remarks: The machine cannot record all the adjusting and monitoring values.

- the purpose、sensor position、type and sampling method of control、measurement and display device

the purpose	sensor position	type	sampling method
Airway pressure	Exhaling end	pressure- voltage、Simulated data	Choose average value from multiple sampling
PEEP	Exhaling end	pressure- voltage、Simulated data	Choose average value from multiple sampling
Continuous pressure	Exhaling end	pressure- voltage、Simulated data	Choose average value from multiple sampling
freq	built-in	time、simulated data	Choose average value from multiple sampling
Inhalation time	built-in	time、simulated data	Choose average value from multiple sampling
Holding time	built-in	time、simulated data	Choose average value from multiple sampling
tidal volume	Exhaling end	flow- voltage、Simulated data	Choose average value from multiple sampling
flow	Exhaling end、inhaling end	flow-voltage、simulated data	Choose average value from multiple sampling
O_2 concentration	Inhaling end	O_2 concentration-voltage、simulated data	Choose average value from multiple sampling

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统一社会信用代码

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若 业执照

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名 称 南京舒普思达医疗设备有限公司

类 型 有限责任公司

注册资本 1921. 2(,?.万兀整

成立日期 2oo,s ir-o t川18ll

法定代表人 楼田甘廿

营业期限 2008什-:0l丿Ji 8 H 5 2028ll\01 ll 171-l

经营范围 仄疗揣城4 产（按许可证队 列项目 4 产、 纾找），从竹湍阤研发； 自材和代即各类商品 |及技术的进出门业务（11家限处企 11J1 经片或禁且进出 !J 的商品和技术除外） ıj戏 侣 仪表的研发、生T". 悄l月，动物川麻 醉，i'f吸、，阤护、养护设 备的研发， 4 j"气、销仆. 机桩设备 、电（ 设备、试验设备制迅 、加 J:ı 如l 生/'、村什 ;t; 软硬门及工业设计 技人咨询、技木服务。（依队孙经批准的项!! . 经相关部 l'J 批准川i h 可开展纾片梧动）

住 所 南京 市i'.J 化勍区 搏京路 0号6'·)楼 压 寸县

登 记 机 关 2019 年 07 月 12 日

国家企业信用信息公示系统网址: http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

医疗器械　产、　可证

许可证编号：苏食药监械生产许20070089号

企业名称：

法定代表人：楼[J]甜　　：产产品 抒记 表

企业负责人：彭家良

住　　所：南京中 江北新区冈富路9号6号楼勹层、二从　　发证部门：江 苏

有效期限：至　2022 年　。1 月　。8 日　　发证日期：　2017　　0 9 日

上 许

南京舒普思达医疗设备有限公司

生产地址：南京市江北
层、三层

生产范围：见医疗器械

省药

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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从 kred 心 ru 心 如 比
D-ZM-11321-01-00

Product Servi倍

Certificate

No. 05 082515 0006 Rev. 00

Holder of Certificate:

Uuhe District

Facility(ies):

NanJing Superstar Medical Equipment Co.. Ltd
The 2nd and 3rd Floors, No6 Building, No.9 Bofu Road, Yan11ang industri al Development Zone . Liuhe District. 211505 Nan jing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate:

Design and Development,
Production and Distribution of
Anaesthesia Systems, Ventil ators ,
CPAP Systems, N20 Sedation Systems,
Air Compressors and Oxygen Concentrators ,
Sleep Therapy Systems

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Qualit't management systems - Requirements for regulatory pu rpo ses
{ISO 13485:2016)
DIN EN ISO 13485:2016

T he Certification Body of TOV SOD P roduct Service GmbH certifies that the company mentioned a bove hases tablished and is maintaining a quality managementsystem, which meetst he requirements of the listed standard(s). See also notes overleaf

Report No.: SH1873607

Valid from: 2019-03-0i
Valid until: 2022-02-28

Date, 2019-02-27

Stefan Preil?.

• Rid!erstrane 65·80339 Munich • Germany